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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/525,633 | 04/10/2006 | Ozkan Yalkinoglu | Le A 36 293 | 3695 |
| <div>35969759011/02/2010</div> <div>Barbara A. Shimei</div> <div>Director, Patents & Licensing</div> <div>Bayer HealthCare LLC - Pharmaceuticals</div> <div>555 White Plains Road, Third Floor</div> <div>Tarrytown, NY 10591</div> | | | | |
| EXAMINER | | | | |
| BASS, DIRK R | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1777 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,633

Applicant(s)

YALKINOGLU ET AL.

Examiner

DIRK BASS

Art Unit

1777

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7-16 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7,8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date 8/6/10
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's request for continued examination, filed August 6, 2010 is acknowledged. Claims 1, 3-5, 7-8, 11-16 are amended, claims 2, 9-10 are withdrawn, and claim 6 is cancelled. Claims 1, 3-5, 7-8, and 11-16 are pending and further considered on the merits.

Response to Amendment

In response to applicant's amendment, the examiner modifies the grounds of rejection in light of Lamping et al., PCT/DE02/01376.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. **Claims 1, 3-4, 7-8, 12-13, and 15-16** are rejected under 35 U.S.C. 102(a) as being anticipated by Lamping et al., PCT/DE02/01376. For purposes of examination, the examiner is relying on the US pre-grant publication of the above PCT, herein after Lamping et al., USPA 2004/0142388 (Lamping).
3. Regarding claims 1 and 3-4, Lamping discloses a method of assessing the state of Alzheimer's disease (abstract) comprising detecting a polypeptide having a molecular mass of 4824 ± 20 Da, wherein the polypeptide is a fragment of VGF (abstract, ¶¶ 0010, 0033-0034, 0036, and Table 1; Seq ID # 27, 29).
4. Regarding claims 7, 13, and 16, Lamping discloses a method wherein the sample comprises CSF (¶ 0059).
5. Regarding claims 8, 12, and 15, Lamping discloses a method wherein specific antibodies recognizing said polypeptides are used to detect said polypeptides (¶¶ 0002, 0041, Claim 16).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 1 and 3-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Landfield et al., USPA 2005/0071088 (Landfield) as evidenced by Lamping
8. Regarding claims 1 and 3-4, Landfield discloses a method of assessing a state of Alzheimer's disease (abstract and ¶ 0006) comprising detecting neurosecretory protein VGF (¶ 0114, Claims 1 and 32).
9. Landfield fails to explicitly disclose the molecular mass of VGF or the particular polypeptide sequence to be detected. However, it would have been obvious to one having ordinary skill in the art at the time of invention was made to detect a specific polypeptide sequence having the disclosed molecular mass, since such polypeptide fragments are known in the prior art, and are used to assess the state of Alzheimer's disease as evidenced by Lamping (abstract, ¶ 0010, 0033-0034, 0036, and Table 1; Seq ID # 27, 29).
10. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lamping.
11. Regarding claim 5, Lamping does not explicitly disclose using two distinct samples from a patient. However, it would have been an obvious matter of design choice to take multiple samples from a patient to detect for Alzheimer's disease, since applicant has not disclosed that doing so solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the method disclosed in Lamping.
12. **Claims 11 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamping in view of Delacourte et al., USPA 2005/0175626 (Delacourte).
13. Regarding claims 11 and 14, Lamping discloses a method utilizing mass spectrometry (see Examples), but does not explicitly disclose the use of SELDI-TOF mass spectrometry. However, Delacourte discloses a method of assessing a state of Alzheimer's disease (Claim 1) comprising separating polypeptides from cerebral spinal fluid samples via antibodies specific for said polypeptides and detecting said polypeptides via SELDI-TOF MS (see Example 3, ¶ 0207-0210).
14. Therefore, at the time of invention, it would have been obvious to a routineer in the art to substitute the MALDI-MS method of Lamping with the SELDI-TOF MS method of Delacourte since all the claimed elements were known in the prior art and one skilled

in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

15. Applicant's arguments with respect to claims 1, 3-4 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1777

/DRB/
Dirk R. Bass